UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 49 HEALTH AND WELFARE FUND, on behalf of itself and all others similarly situated, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD, BARR PHARMACEUTICALS, INC., BARR LABORATORIES INC., DURAMED PHARMACEUTICALS INC. (n/k/a TEVA WOMEN'S HEALTH INC.), DURAMED PHARMACEUTICALS SALES CORP., BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Defendants.	Civil Action No. _____ CLASS ACTION JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff, International Union of Operating Engineers Local 49 Health and Welfare Fund, on behalf of itself and all others similarly situated, files this Class Action Complaint ("Complaint") against Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively "Teva"), Defendants Barr Pharmaceuticals, Inc. and Barr Laboratories Inc. (collectively "Barr"), Defendants Duramed Pharmaceuticals Inc. (n/k/a Teva Women's Health Inc.) and Duramed Pharmaceuticals Sales Corp. (collectively "Duramed"), and Defendants Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim International GmbH, and Boehringer Ingelheim Pharmaceuticals, Inc. (collectively "Boehringer," and with

Teva, Barr, and Duramed, "Defendants"). Plaintiff alleges as follows based on its personal knowledge, the investigation of its counsel; and upon information and belief.

I. NATURE OF THE CASE

1. Plaintiff brings this class action on behalf of a Class of end-payors who, since August 14, 2009, indirectly purchased, reimbursed, or otherwise paid for a drug called Aggrenox, which combines extended-release dipyridamole with acetylsalicylic acid (aspirin) to lower the risk of stroke in patients whose blood clots have caused a transient ischemic attack or stroke. Boehringer conspired with certain manufacturers of generic pharmaceuticals to pay them not to produce and sell a generic equivalent of Aggrenox. This anticompetitive conduct was intended to, and in fact did, prevent a less expensive generic equivalent of Aggrenox from entering the market. Defendants' actions violated state and federal antitrust and consumer-protection law. Plaintiff, and the Class it represents, seeks damages and declaratory and injunctive relief.

2. Boehringer began selling Aggrenox in December 1999. Aggrenox has been a commercial success and a steady source of profit for Boehringer. By 2008, Aggrenox had U.S. sales of approximately $366 million, a figure that rose to approximately $404 million in 2009.

3. In January 2007, Barr sought regulatory approval to market a generic version of Aggrenox. Shortly thereafter, Boehringer sued Barr, alleging that Barr had infringed Boehringer's U.S. Patent No. 6,015,577 (the "'577 patent"), which expires in January 2017. By bringing its lawsuit, Boehringer triggered an automatic stay of the FDA's approval of Barr's generic product that could last up to 30 months.

4. In the course of the patent suit, Barr raised a series of defenses that seriously threatened the validity of Boehringer's '577 patent. The invalidation of Boehringer's patent would not only enable Barr to enter the market with its lower priced generic Aggrenox product,

but also would open the floodgates to competition from other generic manufacturers (including, but not limited to, a less expensive "authorized generic" sold by Boehringer itself, or its licensee).

5. To avoid the loss of its Aggrenox patent (and its Aggrenox monopoly profits), Boehringer engineered a scheme with Barr (later acquired by Teva) pursuant to which Boehringer began paying Barr substantial amounts of money as compensation and consideration for Barr's agreement to drop its challenge to Boehringer's Aggrenox patent and to delay the sale of Barr's lower priced generic version of Aggrenox for a period of seven years.

6. In August 2008, Boehringer and Barr entered into a reverse-payment and market-allocation agreement (commonly known as a "pay-to-delay" agreement) with Barr. Under the terms of that agreement, Barr agreed to drop its challenge to the validity of the '577 patent and not to launch its generic version of Aggrenox before July 1, 2015. In exchange for these actions by Barr, Boehringer entered into a co-promotion agreement with Barr, pursuant to which Barr's subsidiary Duramed would promote Aggrenox to obstetricians and gynecologists during the seven-year period during which Barr had agreed to refrain from selling generic Aggrenox. The co-promotion agreement would bring Barr a substantial amount of money, both from an initial payment as well as from a series of continuing annual payments that were calculated as a percentage of all Aggrenox sales in the United States. Based on Aggrenox's 2008 sales, Barr could expect to receive approximately $120 million over the seven-year co-promotion agreement. Since the settlement's August 2008 execution, Boehringer has continued to make payments to Barr (and to Barr's successor, Teva) pursuant to the terms of the co-promotion agreement.

7. But the co-promotion agreement was purely pretextual — a sham. The initial and continuing payments Boehringer has made to Barr under the deal were far in excess of fair value for those services, considering that, among other things, Boehringer could not have had any reasonable expectation that it would benefit from the targeted promotion of Aggrenox – a drug for stroke patients – to a group consisting primarily of obstetricians and gynecologists. Furthermore, the payments to Barr under the co-promotion agreement were calculated based on *total* Aggrenox sales, not on any increase in sales that might have resulted from Barr's promotional efforts. In sum, the services to be provided by Barr under the pretextual co-promotion agreement were either completely unnecessary or could have easily been provided by Boehringer itself at the same or lesser costs. Boehringer's true purpose for making these substantial payments to Barr under the co-promotion agreement was to compensate Barr for delaying the launch of its generic version of Aggrenox, thereby preserving Boehringer's monopoly until as late as July 2015.

8. The lucrative co-promotion agreement was not a separate, stand-alone transaction that was independent of the settlement. Rather, it was a pretext for a series of ongoing payments to Barr for entering into, and perpetuating, an unlawful market-allocation agreement, pursuant to which Barr agreed not to compete with Boehringer in exchange for a continuing share of Boehringer's monopoly profits from the sale of Aggrenox. In various court papers and court hearings related to a Federal Trade Commission ("FTC") investigation of the settlement, Boehringer admitted that the millions of dollars in ongoing payments to Barr were inextricably tied to the patent-litigation settlement. After reviewing various settlement-related documents, a federal court that had been petitioned to enforce the FTC's subpoena found that the co-promotion agreement was an "integral" part of the settlement. Moreover, Boehringer has admitted not only

that the co-promotion agreement was tied to the settlement, but also that it was "part of the flow of compensation" and "part of the consideration" that Boehringer paid to Barr for agreeing to the settlement, and that the co-promotion agreement "informed" (i.e., affected) the terms on which the parties settled their patent litigation. Finally, Boehringer has stated that the co-promotion agreement was "inextricably intertwined" with the settlement, and that Boehringer would not have been willing to give Barr the initial and continuing payments under the co-promotion agreement while the parties were still engaged in litigation. In other words, Barr's ability to get the $120 million promotional deal from Boehringer was contingent on Barr's agreement to settlement terms (including a much-delayed market-entry date) that were acceptable to Boehringer.

9. The purpose and effect of the substantial ongoing payments under the co-promotion agreement was to compensate Barr for keeping its lower-priced generic product out of the market for a longer period of time than it otherwise would have done. It was far more profitable for Barr to delay its market entry in exchange for a deal that could be worth as much as $120 million over seven years than it would have been to launch a competing generic product sooner but without that compensation. Had Barr declined the initial (or subsequent) payments and launched its generic equivalent sooner, it would have faced stiff competition – first, from an authorized generic version of Aggrenox that Boehringer likely would have started selling immediately to compete with Barr; and later, from other generic manufacturers. Either (much less both) of these events would have caused the generic equivalents to behave like a commodity, and prices for Aggrenox and its generic equivalents would have dropped for both Barr and Boehringer. Such unrestrained competition would have significantly benefitted consumers, who would have enjoyed lower-priced versions of Aggrenox. But it has been far more profitable for

Barr (and Teva) and Boehringer to avoid competing and instead to share Boehringer's monopoly profits from Aggrenox.

10. Despite having received final FDA approval for its generic Aggrenox product in August 2009, Teva (which acquired Barr in December 2008) has not yet launched its generic Aggrenox product in the United States. Absent the payments under the continuing anticompetitive deal, Teva/Barr would already be competing in the market with its lower-priced generic Aggrenox product because either: (a)Teva/Barr and Boehringer would have agreed to a pro-competitive settlement that did not contain illegal financial inducements and, as a result, would contain a license with an earlier market-entry date; (b) Teva/Barr would have launched "at-risk" once the 30-month litigation stay expired; and/or (c) Teva/Barr would have won the patent suit.

11. It is well known within the industry that Teva is the most prolific launcher of generic versions of brand-name drugs on an at-risk basis, that launching at-risk is a core part of its business strategy, that Teva possesses insurance covering portions of that risk, and that as a multibillion-dollar-per-year company, Teva possesses the financial ability to cover any potentially non-insured losses stemming from at-risk launches. It is also well known within the industry that most at-risk launches, or threats of them, give rise to settlements of the associated patent litigation.

12. Because generic versions of brand-name drugs are typically much less expensive than their brand-name counterparts, and because purchasers typically switch rapidly from a brand to a generic once the generic becomes available, wrongful suppression of generic competition, like that which occurred here, results in enormous overcharge damages to end-payor purchasers like Plaintiff and the Class.

13. But for the pay-for-delay agreement, end-payors of Aggrenox would have paid substantially less for generic equivalents of Aggrenox. Defendants have shared in the illegal profits reaped from this scheme. Defendants' agreement was intended to, and in fact did, (a) preclude entry into the market of cheaper generic versions of Aggrenox; (b) fix, raise, maintain, or stabilize the prices of Aggrenox; (c) permit Boehringer to monopolize the U.S. market for Aggrenox, to the exclusion of generic equivalents; and (d) allocate 100% of the U.S. market for 200 mg extended-release dipyridamole/ 25 mg acetylsalicylic acid capsules to Boehringer.

14. On behalf of the Class, Plaintiff seeks a judgment declaring that Boehringer's pay-for-delay agreement with Barr is unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1. Plaintiff also seeks an injunction pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, because, unless enjoined, Defendants' unlawful conduct will continue unchecked, and Plaintiff will continue to suffer financial harm as a result of Defendants' antitrust violations. Plaintiff also asserts claims for compensatory and treble damages and equitable relief for continuing violations of state antitrust laws and for unjust enrichment.

II. JURISDICTION AND VENUE

15. This Court has jurisdiction over this action under 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, there are more than one hundred members of the proposed Class, and at least one member of the proposed Class is a citizen of a state different from that of one of the Defendants.

16. This Court also has jurisdiction over this matter under 15 U.SC. § 26 and 28 U.S.C. §§ 1331 and 1337 because Plaintiff brings claims under section 16 of the Clayton Act, 15 U.S.C. § 26, for injunctive and equitable relief to remedy the Defendants' violations of

Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1-2. The Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. § 1367.

17. This Court has jurisdiction over Defendants because they are present in the United States, do business in the United States, have registered agents in the United States, may be found in the United States, and are otherwise subject to the service of process provisions of 15 U.S.C. § 22.

18. Venue is appropriate within this District under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. § 1391(b) and (c), because Defendants transact business within this District and because their interstate trade and commerce is carried out in substantial part in this District. The acts complained of have and will continue to have substantial effects in this District.

III. PARTIES

A. Plaintiff

19. Plaintiff International Union of Operating Engineers Local 49 Health and Welfare Fund ("Local 49" or "Plaintiff") is a Taft-Hartley fund authorized pursuant to Section 302(c)(5) of the National Labor Relations Act, with its principal place of business in Roseville, Minnesota, and an employee welfare benefit plan as defined in Section 3(1) of ERISA. Local 49 provides health benefits, including prescription drug benefits, to approximately 32,000 active participants and retirees, plus their spouses and dependents. Local 49 purchased and/or provided reimbursement for some or all of the purchase price of Aggrenox, other than for re-sale, in Minnesota and Wisconsin, among other locations, between August 14, 2009 and the present, at supra-competitive prices. As a direct result of its Aggrenox purchases during the Class Period, Local 49 has been injured, paying more than it would have absent Defendants' unlawful scheme to delay the entry of generic equivalents of Aggrenox onto the market.

B. Defendants

20. Defendant Teva Pharmaceuticals USA, Inc., a wholly-owned subsidiary of Teva Pharmaceuticals Industries Limited, is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. It manufactures and distributes generic drugs for sale throughout the United States at the direction, under the control, and for the direct benefit of its parent company.

21. Defendant Teva Pharmaceuticals Industries, Ltd. is a corporation organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, Petach Tikva, Israel. Teva is a leading manufacturer of generic drugs, and is one of the largest sellers of generic drugs in the United States. Teva purchased Barr in 2008, and Barr is now a wholly owned subsidiary of Teva.

22. Defendant Barr Pharmaceuticals Inc. is a corporation organized under the laws of the state of Delaware, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Prior to 2004, Barr was known as Bar Laboratories, Inc. Barr Pharmaceuticals Inc. was purchased by Teva on December 23, 2008 and is now Teva's wholly owned subsidiary.

23. Defendant Barr Laboratories, Inc. is a corporation organized under the laws of the state of Delaware, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. On December 23, 2008, Barr became a wholly-owned subsidiary of Teva.

24. Defendant Duramed Pharmaceuticals Inc. ("DPI") is a corporation organized under the laws of the state of Delaware, with its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. Until 2008, Duramed was a subsidiary of Barr. In December 2008, when Teva purchased Barr, Duramed became a subsidiary of Teva and is now known as Teva Women's Health, Inc.

25. Defendant Duramed Pharmaceuticals Sales Corp. ("DPSC") is a corporation organized under the laws of the state of Delaware, with a principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey. It was a subsidiary of Barr until December 2008, when it became a subsidiary of Teva.

26. Defendant Boehringer Ingelheim Pharma GmbH & Co. KG is a limited partnership organized and existing under the laws of Germany, with its principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

27. Defendant Boehringer Ingelheim International GmbH ("BII") is a limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

28. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a Delaware corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut.

29. All of the Defendants' actions described in this complaint are part of, and were in furtherance of, the illegal restraint of trade alleged herein, and were authorized, ordered, and performed by the Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants' affairs, within the course and scope of their duties and employment, and with the actual, apparent or ostensible authority of the Defendants.

IV. BACKGROUND

A. Generic Drugs Benefit Purchasers

30. The availability of generic drugs has been one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which also must be approved by the FDA, have the same active chemical composition and provide the same therapeutic benefits as

the brand-name drugs upon which they are modeled. The FDA assigns an "AB" rating to generic drugs that are bioequivalent to brand-name drugs.

31. To be deemed a therapeutic equivalent and assigned an "AB" rating by the FDA, the generic drug must contain the same active ingredient(s); the same dosage, form, and route of administration; and the same strength as the brand-name drug. If the generic drug can meet these requirements, and is deemed to be a therapeutic equivalent, it can be substituted (and in many instances, *must* be substituted) for the brand-name drug at the pharmacy that fills the prescription.

32. Typically, AB-rated generic versions of brand-name drugs are priced substantially below their brand-name equivalents. A 1998 study conducted by the Congressional Budget Office (the "CBO") concluded that generic drugs save consumers and third-party or end payors between $8 billion and $10 billion a year. A report prepared by the Government Accounting Office in August 2000 observed, "[b]ecause generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs."

33. The Federal Trade Commission ("FTC") estimates that the first generic manufacturer to enter the market typically charges between 70% and 80% of the price of the brand-name drug. As additional manufacturers bring generic versions of the drug to market, the price for the generic equivalents continue to drop.

34. A brand-name drug loses a significant portion of its market share to generic competitors as soon as the first generic enters the market, even if the brand-name manufacturer lowers its price to meet competition. The 1998 CBO study estimates that generic drugs capture at least 44% of the brand-name drug's market share in just the first year of sale.

35. An AB rating is particularly significant to a generic manufacturer because, under the statutory regime enacted both by Congress (i.e., Hatch-Waxman, discussed infra) and most state legislatures (*i.e.*, Drug Product Selection laws, or "DPS laws"), pharmacists may (and in most states, must) substitute an AB-rated generic version of a drug for the brand-name drug without first seeking or obtaining permission from the prescribing doctor. Indeed, both Congress and the state legislatures have actively encouraged generic substitution because they recognize that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously engaging in expensive marketing and providing low-cost pharmaceuticals to purchasers.

36. Because of the price differentials, and other institutional features of the pharmaceutical market like DPS laws, AB-rated generic versions are rapidly and substantially substituted for their brand-name counterparts. Predictably, when multiple generic manufacturers enter the market, prices for generic versions of a drug decrease significantly because competition among the generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generics, are dramatic and swift.

37. Competition from generic versions of brand-name drugs, as well as competition among various generic versions of brand-name drugs, lowers both the cost of the brand-name drug and the cost of the generic equivalents for end-payors. But until a generic manufacturer enters the market with an AB-rated generic, there is no bioequivalent generic drug permitted to compete with the brand-name drug, and thus the brand-name manufacturer can continue to charge supracompetitive prices without losing sales of its branded product. Consequently, brand-name manufacturers have a strong incentive to use various tactics, including the tactics alleged in this Complaint, to delay introduction of AB-rated generic competition in to the market.

B. The FDA Approval Process

38. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "FDCA"), the FDA must grant its approval before a company may begin selling a new drug. Pre-market approval for a new drug, often referred to as a "pioneer" or "brand-name" drug, must be sought by filing a New Drug Application ("NDA") with the FDA, demonstrating that the drug is safe and effective for its intended use. New drugs that are approved for sale in the United States by the FDA are typically (but not necessarily) also covered by patents, which provide the patent owner with the exclusive right to sell that new or pioneer drug in the United States for the duration of any patents involved, plus any extension of the original patent period (the "FDA Exclusivity Period") granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, 21 U.S.C. § 355 ("Hatch-Waxman Act").

39. In addition to information on safety and efficacy, NDA applicants must submit to the FDA a list of all "prior art," as well as patents that claim the drug for which FDA approval is being sought or which claim a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted. "Prior art" is the term used in patent law to refer to that body of previous knowledge and technology against which a patent application is judged to determine whether the claim is sufficiently novel to merit patent protection. When the NDA is approved, the FDA "shall publish" the patent information submitted by the NDA applicant. 21 U.S.C. § 355(b)(1).

40. Once the NDA is approved, the FDA lists any patents the NDA applicant has referenced as part of the application process in a publication known as the *Approved Drug Products With Therapeutic Equivalence Evaluations*. This publication is commonly called the "Orange Book." FDA's listing of patents in the Orange Book is purely of ministerial act. The

FDA does not check the facts supplied to it by the brand-name manufacturer, and instead trusts that the manufacturer has been truthful.

41. Once a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name. A licensed pharmacist must fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of that pioneer drug which has been approved by the FDA is available.

C. The Government Encourages and Facilitates the Approval Of Generic Drugs Through the Hatch-Waxman Amendments

42. As described above, generic drugs are drugs that the FDA has found to have the same active chemical composition and provide the same therapeutic effects as the brand-name drugs. Where a generic drug is bioequivalent to a brand-name drug, the FDA assigns the generic drug an "AB" rating.

43. If a generic version of a brand-name drug exists and the physician has not specifically indicated on the prescription "DAW" or "dispense as written" (or similar indications, the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing the branded drug, or the less expensive AB-rated generic.

44. Once a physician writes a prescription for a brand-name drug, such as for Aggrenox, only those drugs that carry the FDA's AB generic rating may be substituted by a pharmacist for a physician's prescription for a brand-name drug. Thus, that prescription defines and limits the market to the drug named or its AB-rated generic equivalent.

45. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development and approval of generic drugs. Consumers benefit from the choice and competition provided by generic drugs. Hatch-Waxman simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to gain FDA approval for their products. Instead, the FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA"). The ANDA may rely on the scientific findings of safety and efficacy that the brand-name manufacturer included in its original NDA, if the ANDA applicant can demonstrate that the proposed generic drug is "bioequivalent" to the corresponding brand-name drug — that is, that it delivers the same amount of active ingredient into the body at the same rate as does the brand.

46. As a counter-balance, Hatch-Waxman also streamlined the process for a brand-name manufacturer to enforce its patents against infringement by generic manufacturers, and provided the brand-name manufacturer with the option to exercise what is essentially an automatic, non-judicial preliminary injunction, in the form of a 30-month stay of FDA approval of a generic manufacturer's ANDA.

47. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a brand-name drug), a generic manufacturer must certify that the generic drug addressed in its ANDA will not violate any patent listed in the Orange Book as claiming the brand-name drug. Thus, under Hatch-Waxman, the ANDA must contain one of four certifications:

a. that no patent for the pioneer drug has been filed with the FDA (a "paragraph I certification");

b. that the patent for the pioneer drug has expired (a "paragraph II certification");

c. that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "paragraph III certification"); or

d. that the patent for the pioneer drug is invalid or will not be infringed upon by the proposed generic company's product (a "paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant's only certification options are paragraph III or IV certifications.

48. If the ANDA contains paragraph IV certification, the ANDA applicant must provide notice to the owner of each patent that is referred to in the certification, and to the holder of the approved NDA to which the ANDA refers. *See* 21 U.S.C. § 355(j)(2)(B)(I). The notice must include a detailed statement of the factual and legal basis for the ANDA applicant's assertion that the patent is not valid or will not be infringed by the generic product. *See id.*; 21 C.F.R. § 314.95.

49. The filing of an ANDA with a paragraph IV certification gives rise to a cause of action for patent infringement. 35 U.S.C. § 271(e)(2)(A). If the patent owner initiates an infringement action against the ANDA filer within 45 days, then the FDA may not issue final approval of the ANDA until either 30 months thereafter or until a court has ruled that the patent is invalid or is not infringed by the generic manufacturer's ANDA – whichever is later. 21 U.S.C. § 355(j)(5)(5)(iii). But if no action is initiated within 45 days, the process for FDA approval of the generic product is not delayed by patent issues, and the FDA may grant final approval of the ANDA once it has satisfied itself as to the safety and efficacy of the generic drug. Accordingly, the timely filing of an infringement action provides the patent owner with the equivalent of a 30-month automatic preliminary injunction.

50. To encourage generic manufacturers to challenge branded drug patents or to design around them, Hatch-Waxman grants the first paragraph IV ANDA filer a 180-day

exclusivity period to market the generic version of the drug, during which time the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand-name drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). This 180-day exclusivity against other generic competitors is awarded to the first Paragraph IV filer regardless of whether or not the brand-name company institutes pre-approval patent infringement litigation in response to the paragraph IV certification.

D. Brand-Name Manufacturers Game the Regulatory Structure

51. Because of the FDA rules described above, brand-name manufacturers have an incentive to list patents in the Orange Book even if those patents do not satisfy the appropriate criteria for listing, and to then sue any generic competitor that files an ANDA with paragraph IV certification even if such competitor's product does not actually infringe the listed patent. The reason for this is simple: those actions result in a delay of final FDA approval of an ANDA for up to 30 months. In addition, prior to a recent change in the Hatch-Waxman regulations, brand companies could, and did, bring multiple infringement suits (based on multiple patents listed in the Orange Book) against a single ANDA, thereby obtaining independent 30-month stays associated with each suit. This practice was curtailed by a change in FDA regulations mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which, due to repeated abuses by brand manufacturers of the type described here, limited brand manufacturers to a single stay per ANDA. *See* 21 C.F.R. §§ 314.52, 314.95, 314.107(b)(3)(i)(A).

E. No-Authorized-Generic Agreements

52. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand-name drug during that l80-day period. Such an "authorized generic" is chemically identical to the brand drug, but is sold as a generic product through either a brand-name manufacturer's

subsidiary or through a third-party generic manufacturer. While competition from an authorized generic during the 180-day exclusivity period substantially reduces the first-filer's revenue, it also substantially reduces drug prices for consumers.

53. In its recent study entitled *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011) (the "FTC Study"), the FTC found that authorized generics capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because the presence of an additional generic in the market causes prices to decrease and because the authorized generic takes a large share of unit sales away from the first filer.

54. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, consumers and other drug purchasers, such as Plaintiff and the Class, benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

55. Given the significant downward effect of an authorized generic on the first-filing generic's revenues, a brand manufacturer's agreement not to launch an authorized generic has tremendous value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such non-competition agreements deprive consumers and other drug purchasers, such as Plaintiff and the Class, of the lower prices resulting from two forms of competition: first, competition between the branded and the generic products; and second, competition among the generic products.

56. Agreements not to compete through an authorized generic can take many forms. According to the FTC Study, one such form includes agreements whereby the brand-name

manufacturer agrees to supply the first-filing generic with the authorized generic product exclusively. The result is that there exists no competition between an authorized generic and the first-filing generic's product for a period of time.

V. THE AGGRENOX PAY-FOR-DELAY AGREEMENT

A. Boehringer Starts Marketing Aggrenox in December 1999

57. Boehringer developed Aggrenox as a treatment to lower the risk of stroke in patients who have had a transient ischemic attack (also known as a "mini-") or stroke due to a blood clot. A transient ischemic attack is similar to a stroke, except it usually lasts only a few minutes and does not result in permanent damage.

58. Aggrenox is a single gelatin capsule containing 200mg of extended-release dipyridamole and 25mg of immediate-release acetylsalicylic acid (aspirin). Boehringer has previously marketed dipyridamole as a stand-alone drug under the brand name Persantine to prevent clots from forming after heart valve replacements, and aspirin has previously been prescribed for the prevention of strokes. Boehringer holds NDA No. 20-884, under which the FDA granted approval in 1999 for 200 mg extended-release dipyridamole/ 25 mg acetylsalicylic acid capsules.

59. Either directly or through its affiliates BII and BIPI, Boehringer owns the '577 patent, which issued on January 18, 2000, and is entitled "Pharmaceutical Compositions Containing Dipyridamole or Mopidamol and Acetylsalicylic Acid of the Physiologically Acceptable Salts Thereof, Processes for Preparing Them and Their Use in Treating Clot Formation." The '577 Patent is scheduled to expire on January 18, 2017. After receiving FDA approval of its drug, Boehringer listed the '577 patent in the "Orange Book" as pertaining to Aggrenox.

60. Boehringer began marketing Aggrenox in December 1999. Aggrenox was the only prescription drug for reducing the risk of subsequent stroke through a single aspirin and extended-release dipyridamole capsule. Studies submitted to the FDA by Boehringer showed that Aggrenox's combined dipyridamole-aspirin formulation is more effective at reducing the risk of future stroke than administration of either active ingredient on its own.

61. Aggrenox quickly became a commercial success and a steady source of profits for Boehringer. By 2008 Aggrenox sales in the United States had reached $366 million per year.

B. Barr Seeks FDA Approval to Market a Generic Equivalent to Aggrenox; Boehringer Sues Barr

62. In May 2007, Barr submitted ANDA No. 78-804 to the FDA, seeking approval to market a generic equivalent of Aggrenox. On May 31, 2007, Barr notified Boehringer that it had submitted ANDA 78-804, and that its ANDA contained a paragraph IV certification that the commercial use and sale of its own generic Aggrenox product would not infringe any valid and enforceable claim of the '577 patent. As the first filer of an ANDA for generic Aggrenox, Barr is entitled to market generic Aggrenox for 180 days free from competition from other ANDA-based generic Aggrenox products. That exclusivity does not, however, protect Barr from competition in the form of a less expensive "authorized generic" version of Aggrenox, as sold by Boehringer itself or Boehringer's licensee.

63. On July 11, 2007, Boehringer sued Barr in the United States District Court for the District of Delaware (Case No. 07-cv-00432), alleging that Barr's filing of its ANDA infringed the '577 patent. Boehringer's infringement suit triggered the 30-month stay that prohibited the FDA from granting Barr final approval to launch a generic equivalent of Aggrenox either until the court issued a final judgment that the '577 patent was invalid or not infringed, or until November 30, 2009, whichever came first.

64. Barr denied the allegations in Boehringer's complaint and counterclaimed, seeking a declaratory judgment that the '577 patent was invalid, that Barr's proposed generic did not infringe the '577 patent, and that the '577 patent was unenforceable due to Boehringer's own inequitable conduct. More specifically, Barr argued that Boehringer had misrepresented to the U.S. Office of Patents and Trademarks ("USPTO") the nature and materiality of a prior patent – Patent No. 5,694,024 - and its related reference DE-AI-3,515,874. According to Barr, had Boehringer properly disclosed that patent and its related reference, the claims of the '577 patent would have been obvious. In light of these allegations, Barr asked the District Court to find the '577 patent unenforceable. The patent lawsuit continued until August 2008 without any substantive rulings. But Barr's defenses and counterclaims were strong, and, had the parties not settled, Barr ultimately would have prevailed in the litigation.

65. Barr's success in the litigation as to the validity of Boehringer's patent would have not only enabled Barr to start competing in the market with its lower priced Aggrenox product, but also would have opened the flood gates to competition from other generic manufacturers (including, but not limited to, a potential authorized generic sold by Boehringer). Because generic versions of brand-name drugs are typically much less expensive than their brand-name counterparts, Boehringer's monopoly prices and profits would quickly end once Barr or other lower priced generic versions of Aggrenox entered the market.

C. Boehringer and Barr Enter Into the Anti-Competitive Agreements

66. To avoid the loss of its Aggrenox patent and its related monopoly profits, Boehringer engineered a scheme with Barr under which Boehringer paid Barr substantial amounts of money over a seven-year period as compensation and consideration for Barr (1) dropping its challenge to Boehringer's patent, and (b) refraining from selling a lower-priced generic version of Aggrenox for seven years.

67. On August 11, 2008, Boehringer and Barr announced that they had settled the patent litigation. On August 13, 2008, Boehringer and Barr filed a stipulation seeking dismissal of the patent litigation with prejudice in light of the settlement. The Court entered the stipulation and dismissed the case the next day.

68. Under the terms of the settlement, Boehringer and Barr agreed that Barr would delay launching a generic equivalent of Aggrenox until at least July 1, 2015 — effectively preserving branded Aggrenox's market exclusivity for approximately 82% of the then-remaining life of the '577 patent (which expires in January 2017).

69. In exchange for Barr's agreement to drop its challenge to Boehringer's patent and not to launch its lower priced generic product for the next seven years, Boehringer agreed to share a portion of its monopoly profits on Aggrenox with Barr during that time through a pretextual "co-promotion" agreement (the "Exclusion Payment Agreement").

70. The Exclusion Payment Agreement between Boehringer and Barr had several components:

a. Settlement Agreement. As described above, Boehringer and Barr agreed to dismiss all claims and counterclaims in the patent litigation, and Barr agreed to delay launching a generic version of Aggrenox until July 1, 2015.

b. Authorized-Generic License. Boehringer agreed to grant Barr a license to market an authorized generic version of Aggrenox under Boehringer's NDA. Absent the agreement, Boehringer had the financial incentive and legal ability to launch an authorized generic version of Aggrenox and to compete against Barr for sales of generic Aggrenox even during the 180-day exclusivity period provided by Hatch-Waxman. The intended result of the agreement as to the authorized-generic license was that Boehringer would not compete against Barr with Boehringer's own authorized generic Aggrenox product, and thus Barr would have no generic competition for its generic Aggrenox product during the 180-day exclusivity period — not even from Boehringer. This aspect of the agreement provides substantial compensation to Barr, because if there is no competing authorized-generic in the market during the 1800-day period, Barr can expect to make

approximately double the unit sales, at a much higher price. These higher prices come at the expense of Plaintiff and the Class.

c. Co-Promotion Agreement. Boehringer agreed to pay Barr (through its subsidiary) for co-promotion services related to sales of Aggrenox. Boehringer agreed to train Duramed's 93-person Specialty Sales Force to promote Aggrenox to obstetricians, gynecologists, and women's health care professionals, beginning in March 2009 and continuing until Barr's generic product entered the market. In exchange, Boehringer agreed to pay Barr a one-time fee plus annual, increasing royalties calculated based on the total U.S. Aggrenox sales for a period of years. The total value of these payments is an estimated $120 million.

D. Teva Acquires Barr and Continues the Scheme

71. On December 23, 2008, Teva acquired Barr. Barr became a wholly owned subsidiary of Teva, and Teva acquired Barr's rights and responsibilities under the Exclusion Payment Agreement. Pursuant to that Exclusion Payment Agreement, Teva has continued to stay out of the market with a generic Aggrenox. Teva thus joined the ongoing unlawful course of conduct — and joined the unlawful agreements, collusion and conspiracy — to suppress generic competition of Aggrenox. Teva did not withdraw from the conspiracy, and instead, continued to participate in it.

72. As a result of its acquisition of Barr, Teva owns (either directly or indirectly) ANDA 78-804 and the 180-day exclusivity period that Barr may be entitled to as the first filer.

73. On August 14, 2009, the FDA granted Teva final approval of ANDA 78-804 for a generic equivalent of Aggrenox, and noted that Teva/Barr may have forfeited its 180-day exclusivity for failing to receive tentative approval within the requisite 30 months. Because of the Exclusion Payment Agreement, no generic equivalent of Aggrenox is currently on the market, and none will be until July 1, 2015.

74. During the period from the date of the Exclusion Payment Agreement until the present, Boehringer has more than doubled the price for Aggrenox.

E. FTC Opens An Investigation And Unearths New Details Of The Exclusion Payment Agreement

75. Under the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA"), the settlement and co-promotion agreements were required to be filed with the FTC. On January 15, 2009, the FTC issued a Resolution Authorizing Use of Compulsory Process in Nonpublic Investigation to determine "whether Boehringer Ingelheim Pharmaceuticals, Inc. and Barr Pharmaceuticals, Inc., and their affiliates, or any other person, has engaged or is engaging in unfair methods of competition . . . with respect to the sale of Aggrenox or its generic equivalents and Mirapex and its generic equivalents." FTC File No. 091-0023; *see Federal Trade Commission v. Boehringer Ingelheim Pharmaceuticals, Inc.*, Case No. 1:09-mc-00564-JMF, Dkt. No. 1-1, at 3 (D.C.). As the FTC explained, "[c]ompensation rarely takes the form of explicit cash payments; instead, the settling firms typically include the payment in a separate business deal executed simultaneously with the settlement." Case No. 12-5393 (D.C. Cir.), Brief of Appellant Federal Trade Commission, Dkt. No. 1444255, p. 9 ("FTC Brief").

76. Pursuant to Sections 3 and 9 of the FTC Act, 15 U.S.C. §§ 43 and 49, on February 5, 2009, the FTC issued a subpoena to Boehringer seeking 37 categories of documents, including documents related to the settlements of the Aggrenox litigation and the co-promotion agreement. The FTC subpoena seeks — and Boehringer has refused to provide — its internal financial analysis regarding whether the payments Boehringer made to Barr under the co- promotion agreement were for promotional services alone, or were in fact "side-payments for an anticompetitive agreement to delay generic entry and share the ensuing monopoly profits." FTC Brief at 2.

77. Boehringer refused to produce documents that would support its claim or substantiate its assertion that the co-promotion agreement provided Boehringer with substantial

value aside from the benefits it derived from delaying generic competition for Aggrenox. In response, the FTC filed a petition to enforce the subpoena. The FTC's petition did not specify the size of the payments from Boehringer to Barr under the co-promotion agreement.

78. On December 12, 2012, after the District Court had determined that Boehringer's internal financial analyses regarding the co-promotion agreement were privileged and in large part denied the FTC's petition, the agency filed a Notice of Appeal with the United States Court of Appeals for the District of Columbia.

79. Although Boehringer has not provided the FTC with its internal financial analyses, the FTC does possess the terms of the co-promotion agreement. Based on that information, the FTC described the payments under the co-promotion agreement as a "significant financial transaction." *Id.* at 36, n. 12. In a June 28, 2013, brief to the United States Court of Appeals for the District of Columbia, the FTC argued that, "under the agreement, Boehringer agreed to pay Barr a one-time fee plus annual, increasing royalties on the total U.S. Aggrenox sales for a period of years . . . In 2008, Aggrenox had total U.S. sales of about $366 million . . . At this level of sales, the FTC estimates that the deal would ultimately cost Boehringer over $120 million in royalties." *Id.*

80. Notably, the filings in the FTC subpoena-enforcement action reveal that the amounts Boehringer has paid, and continues to pay, to Teva/Barr under the co-promotion agreement were not based on the extent to which Teva/Barr's promotional services increased Aggrenox's sales, as would be expected with a fair-value-for-services promotion agreement.

81. Furthermore, the co-promotion agreement was not a fair-value-for-services agreement because Boehringer reasonably could not have had an expectation of receiving significant financial benefit from Barr subsidiaries Duramed and DPSC's promotion of

Aggrenox — a drug for patients who have suffered strokes or mini-strokes — to a group consisting primarily of obstetricians and gynecologists. Also, Barr was not providing any service to Boehringer that Boehringer could not do itself, at the same or lesser cost.

82. The record in the FTC subpoena-enforcement action against Boehringer underscores the following facts:

- The co-promotion agreement arose during the settlement of the '577 patent;
- The continuing payments called for in the co-promotion agreement were "inextricably intertwined with [the] settlement negotiations" in the patent litigation;
- continuing payments called for in the co-promotion agreement were part of "the flow of compensation" and "part of the considerations of the settlement" of the patent litigation; and
- Boehringer would not have agreed to make the initial and continuing payments to Barr under the lucrative co-promotion agreement had Barr not agreed to settle the patent case on terms that were acceptable to Boehringer (i.e., Boehringer would not have made the initial and continuing payments to Barr under the co-promotion agreement unless Barr had agreed to delay the launch of its generic version of Aggrenox for seven years).

83. In litigation with the FTC regarding the agency's investigation of Boehringer and Barr's agreements, Boehringer's counsel admitted that the co-promotion agreement was the means by which Boehringer paid Barr to drop its patent challenge and delay its launch of generic Aggrenox. He described it as "part and parcel of the settlement. It was part of the flow of compensation. It was part of the consideration of the settlement, so it is really a mischaracterization or misdescription to say that we said it was stand alone."

84. At other points, Boehringer's counsel explained that:

a. The settlement agreement and co-promotion agreement "were executed together. The evidence is replete that [the co-promotion agreement was] part of the settlement"; and

b. "We have always said that the Aggrenox co-promote was part of the settlement. It had - It absolutely was."

85. The co-promotion agreement was not a stand-alone business transaction, as evidenced by the fact that Boehringer's payments under the co-promotion agreement vastly exceed the value of the services provided by Barr and its subsidiaries.

86. According to Boehringer's own counsel, documents related to the co-promotion agreement "provide a blueprint for how a company can extract settlement payments out of not only our client, but virtually every branded pharmaceutical company."

87. Magistrate Judge John M. Facciola denied the FTC's motion to compel, finding that the continuing co-promotion agreement, with its substantial ongoing payments to Barr, was "integral" to the settlement of the patent litigation.

88. In 2012, the FTC appealed the district court's ruling. In its August 28, 2013 appellee brief, Boehringer stated that "[i]t is not difficult to understand why parties engaged in contentious litigation would not otherwise be willing to do business with each other." This statement reflects that Boehringer "would not otherwise be willing" to enter into the co-promotion agreement, with its ongoing, substantial payments to Barr, so long as the patent litigation was pending. In other words, unless and until Barr agreed to settlement terms that were acceptable to Boehringer, Barr would not have been able to get the co-promotion agreement and its lucrative payments throughout the seven-year delay period. Indeed, Boehringer stated in that same brief that the co-promotion agreement was "inextricably intertwined with settlement negotiations."

F. Barr's Willingness To Delay Entry In Exchange For Lucrative Side-Deal Payments Was Consistent With Its Past Practices

89. Such transactions were not uncommon for Barr. Bruce Downey, Barr's CEO during the settlement negotiations with Boehringer, stated in a January 17, 2007 written

statement to the U.S. Senate regarding the topic, "Paying Off Generics to Prevent Competition with Brand-Name Drugs: Should It Be Prohibited?":

> Consideration in addition to early entry can be useful in bridging the gap between the generic company's proposed entry date and the branded company's proposed entry date. A branded company that is dead set against an earlier entry date may nevertheless be willing to provide economic value other than early entry in order to persuade the generic company to accept a later entry date.

90. Downey also gave oral testimony at the Senate hearing on January 17, 2007 in which he made the following statements regarding Barr's practices:

> The collateral agreements that narrow the gap are not always cash payments. In fact, they rarely are in our case. They involve some other asset that has a different value for us than it does the brand. Sometimes, for example, we have purchased a product from the brand at a price we think is favorable — it is an asset that is not key to them — as part of the settlement where we have shortened the patent life. In other cases, we have licensed a patent from a brand as part of a settlement where we have shortened the patent life. In other cases, we have agreed to co-promote products for the brand company as part of the settlement where we have shortened the patent life. In other cases, we have entered into an R&D agreement with a brand company as part of a settlement where we shortened the patent life.

See Paying Off Generics to Prevent Competition with Brand-Name Drugs: Should it be Prohibited?, Hearing before the S. Comm. on the Judiciary, 110th Cong., at 28 (Jan. 17, 2007) Serial No. J-110-4 (U.S. Gov't Printing Office).

91. This added "value" to "bridge the gap" that Downey described in his testimony comes solely at the expense of purchasers like Plaintiff and the Class when generic entry is delayed and brand exclusivity is extended as a result.

G. The Unlawful Agreement to Suppress Generic Competition Is Ongoing and Continues to Cause Harm

92. Currently, no generic equivalent of Aggrenox is available in the U.S. Another generic manufacturer has filed an ANDA for generic Aggrenox that includes a paragraph IV

certification for the '577 Patent, but the 30-month stay will not conclude prior to July 2015. Thus, no generic Aggrenox product will enter the market prior to July 2015. If Teva is found eligible for 180 days of marketing exclusivity and launches a generic equivalent of Aggrenox on July 1, 2015, the earliest another company can introduce a generic equivalent of Aggrenox is December 2015.

93. But for the parties' ongoing performance under the reverse-payment and market-allocation agreements, generic competition for Aggrenox would have occurred earlier, and prices for both branded and generic versions of Aggrenox would have been lower. The lack of generic competition is the direct result of the ongoing unlawful agreement that began in August 2008, and will continue at least through July 1, 2015. Boehringer continues to sell brand-name Aggrenox at artificially inflated prices.

94. During the four-year period prior to the filing of this complaint, the Defendants' unlawful conduct was ongoing and the Plaintiff and the Class were injured every day that the Defendants' unlawful agreement was in place. Absent this judicial remedy, Plaintiff and the Class will continue to be overcharged until at least July 1, 2015.

95. But for the anticompetitive, illegal, and ongoing conduct alleged in this complaint, Plaintiff and the Class would have had access to less expensive versions of Aggrenox much sooner. The Defendants have injured Plaintiff and the Class by causing them to pay hundreds of millions of dollars of overcharges on their purchases of Aggrenox.

VI. MARKET CHARACTERISTICS FOR AGGRENOX

96. At all relevant times, Boehringer has had the power to maintain the price of Aggrenox at monopolistic levels without losing substantial sales to competing generic equivalents.

97. Aggrenox does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than an AB-rated generic equivalent of Aggrenox.

98. Because of its unique profile as a combined aspirin and extended-release dipyridamole treatment for subsequent strokes, Aggrenox is differentiated from all products other than AB-rated generic equivalents of Aggrenox. Aggrenox's specific ratio of dipyridamole to aspirin and the release formulations of those components also differentiate it from products aside from AB-rated generic equivalents.

99. Boehringer needed to control only Aggrenox (and any AB-rated generic equivalents to Aggrenox), and no other products, to profitably maintain the price of Aggrenox at monopolistic prices. Only the market entry of a competing AB-rated generic equivalent to Aggrenox would render Boehringer unable to profitably maintain monopolistic prices of Aggrenox without losing substantial sales.

100. Boehringer also sold branded Aggrenox at prices well in excess of marginal costs and the competitive price, and enjoyed high profit margins.

101. The Defendants have had and continue to exercise the power to exclude generic competition to branded Aggrenox.

102. At all relevant times, the Defendants enjoyed high barriers to entry with respect to the market for Aggrenox products due to patent and other regulatory protections, and further due to the high costs of entry and expansion.

103. To the extent that Plaintiff is legally required to define a relevant product market; Plaintiff alleges that the relevant market is all Aggrenox products, which includes Aggrenox and all AB-rated bioequivalent products. During the relevant time period, Defendants have been able to profitably maintain the price of Aggrenox well above competitive levels.

104. The relevant geographic market is the United States and its territories.

105. At all relevant times, Boehringer has had a 100% market share in the relevant market, and will continue to have that 100% market share until July 2015.

VII. MARKET EFFECTS OF DEFENDANTS' ANTICOMPETITIVE SCHEME

106. Boehringer began marketing Aggrenox in December 1999. No generic equivalent of Aggrenox has ever been available for purchase in the United States. Defendants' anticompetitive scheme had the purpose and effect of unreasonably restraining and injuring competition by protecting Aggrenox from generic competition. But for the unlawful Exclusion Payment Agreement: (a) Barr would have entered the market upon receiving final FDA approval or agreed to an unrestrained licensed entry date much earlier than July 1, 2015; and (b) Boehringer would have launched an authorized generic version of Aggrenox simultaneously with the launch of Barr's generic Aggrenox product.

107. But for the Defendants' illegal conduct, Plaintiff and the Class would have paid less for Aggrenox. The Defendants' conduct directly injured Plaintiff and the Class because it forced them to pay hundreds of millions of dollars in overcharges on their Aggrenox purchases.

108. As a result of the delay in generic competition brought about by the Defendants' anticompetitive scheme, Plaintiff and the Class paid more for Aggrenox products than they would have paid absent the Defendants' illegal conduct

109. Barr, and its successor Teva, had extensive experience in the pharmaceutical industry, including experience obtaining approval of ANDAs, manufacturing commercial launch quantities adequate to meet market demand, and marketing generic pharmaceutical products.

110. Upon entering the market, generic equivalents of brand name drugs are priced significantly below the branded drug to which they are AB-rated. When multiple generic

products are on the market, prices for generic equivalents fall even further because of the increased competition.

111. If generic competition for Aggrenox had not been unlawfully delayed, end payors would have paid less for Aggrenox by substituting purchases of less-expensive AB-rated generic equivalents of Aggrenox for their purchases of more-expensive brand Aggrenox.

112. Thus, the Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

VIII. ANTITRUST IMPACT OF DEFENDANTS' SCHEME

113. During the relevant period, Plaintiff and the Class purchased substantial amounts of Aggrenox indirectly from Boehringer. As a result of the Defendants' illegal conduct, these purchasers were compelled to pay artificially inflated prices for Aggrenox. Those prices were substantially higher than the prices that Plaintiff and the Class would have paid absent the illegal conduct alleged in this complaint.

114. As a consequence, purchasers of Aggrenox have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount, forms, and components of such damages will be calculated after discovery and upon proof at trial.

115. Defendants' efforts to restrain competition in the market for Aggrenox have substantially affected interstate and foreign commerce.

116. At all material times, Boehringer manufactured, promoted, distributed, and sold substantial amounts of Aggrenox in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Defendants' anticompetitive conduct had substantial intrastate effects in every state of purchase in that, among other things, retailers within each state were foreclosed from offering cheaper generic equivalents of Aggrenox to

purchasers within each state, which directly impacted and disrupted commerce for consumers and third-party payors within each state.

117. At all material times, Defendants transmitted funds and contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Aggrenox.

118. Economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. *See* Hovenkamp, Federal Antitrust Policy: The Law of Competition and Its Practice (1994) at 624. Professor Herbert Hovenkamp explains that "[e]very person at every stage in the chain will be poorer" as a result of the anticompetitive price at the top. He also says that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

119. The institutional structure of pricing and regulation in the pharmaceutical drug industry ensures that overcharges at the higher level of distribution are passed on to end payors. Wholesalers and retailers passed on the inflated prices of Aggrenox to Plaintiff and the Class.

120. Defendants' anticompetitive conduct enabled Boehringer to indirectly charge consumers and third-party payors prices in excess of what it otherwise would have been able to charge absent the Defendants' unlawful actions.

121. Aggrenox prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

122. The inflated prices that Plaintiff and the Class have paid are traceable to, and the foreseeable result of, the overcharges by Boehringer and the complicit activities of the other Defendants.

IX. CLASS ACTION ALLEGATIONS

123. Local 49, on behalf of itself and all proposed Class members, seeks injunctive and equitable relief and damages, measured as overcharges, trebled, against the Defendants.

124. Plaintiff brings this action on behalf of itself and, under Federal Rule of Civil Procedure 23(a), (b)(2), and (b)(3), as representative of a Class defined as:

> All persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price for Aggrenox, in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, from August 14, 2009 through and until the anticompetitive effects of defendants' unlawful conduct cease.

125. The following persons or entities are excluded from the proposed Class:

a. Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;

b. All governmental entities, except for government-funded employee benefit plans;

c. All persons or entities who purchased Aggrenox for purposes of resale or directly from the defendants or their affiliates;

d. Fully insured health plans (plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);

e. Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs); and

f. The judges in this case and any members of their immediate families.

126. The Class members are so numerous that joinder is impracticable. There are thousands of Class members, both consumers and health plans.

127. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all Class members were damaged by the same wrongful conduct of the Defendants, in that they paid artificially inflated prices for Aggrenox and were deprived of the benefits of earlier and

more robust competition from cheaper generic equivalents of Aggrenox as a result of the Defendants' wrongful conduct.

128. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are not antagonistic to, those of the Class.

129. Plaintiff has retained counsel with experience in the prosecution of class action antitrust litigation, and with experience in class action antitrust litigation involving pharmaceutical products.

130. Questions of law and fact common to the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, making overcharge damages with respect to the Class as a whole appropriate.

131. Questions of law and fact common to all Class members include:

a. Whether Boehringer entered into a contract, combination, or conspiracy with Barr and its affiliates to restrain trade and, if so, whether it should be evaluated under the rule of per se illegality, the "rule of reason," or some other rule or standard;

b. Whether Teva joined the unlawful agreement on its own behalf and on behalf of Barr;

c. Whether Defendants unlawfully excluded competitors and potential competitors from the market for Aggrenox;

d. Whether Defendants unlawfully delayed or prevented generic manufacturers from coming to market in the United States;

e. Whether Defendants' conduct substantially affected interstate commerce;

f. Whether, and to what extent, Defendants' conduct caused antitrust injury to Plaintiff and the Class; and

g. The aggregate amount of overcharge damages to be awarded to the Class.

132. Class action treatment is a superior method for the fair and efficient adjudication of this case. Class treatment will permit a large number of similarly situated, geographically dispersed persons and entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class-action mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in the management of this class action.

133. Plaintiff knows of no special difficulty to be encountered in litigating its claims that would preclude the maintenance of this case as a class action.

X. FRAUDULENT CONCEALMENT TOLLED THE STATUTE OF LIMITATIONS

134. Plaintiff and Class members had no knowledge of the Defendants' unlawful self-concealing scheme and could not have discovered the scheme and conspiracy through the exercise of reasonable diligence more than four years prior to the filing of this complaint.

135. This is true because the nature of Defendants' conspiracy was self-concealing and because the Defendants employed deceptive practices and techniques of secrecy to avoid detection of, and fraudulently to conceal, their contract, combination, conspiracy, and scheme. Notwithstanding the self-concealing nature of their conspiracy, Defendants and their co-conspirators wrongfully and affirmatively concealed the existence of their continuing combination and conspiracy from Plaintiff and Class members by, among other things:

a. Concealing the amounts that Boehringer was to pay and did in fact pay Barr/Teva under the Exclusion Payment Agreement;

b. Concealing the fact that the purpose of the payments under the co-promotion agreement was to provide compensation to Barr/Teva in connection with the settlement of the '577 Patent litigation and the entry date for Barr/Teva's generic product;

c. Concealing the fact that those amounts far exceeded any lawful economic benefit that Boehringer received from Barr/Teva under the agreement; and

d. Filing documents with the SEC that failed to disclose the existence or nature of the Exclusion Payment Agreement. For example, Teva's fiscal year 2008 20-F did not mention the settlement of the Aggrenox litigation. The 20-F mentioned a co-promotion agreement for a different pharmaceutical product, but did not mention the Aggrenox co-promotion agreement. Teva's 20-F filings for the fiscal years 2009, 2010, 2011, and 2012 similarly failed to disclose the Aggrenox settlement or the co-promotion agreement.

136. Because the alleged conspiracy was both self-concealing and affirmatively concealed by Defendants and their co-conspirators, Plaintiff and the Class had no knowledge of the conspiracy more than four years prior to the filing of this Complaint, or of the facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed.

137. Plaintiff and the Class also lacked the facts and information necessary to form a good-faith basis for believing that any legal violations had occurred, including the amounts of payments made from Boehringer to Barr/Teva under the co-promotion agreement. Reasonable diligence on the part of Plaintiff and the Class would not have uncovered those facts more than four years prior to the filing of this Complaint.

138. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiff and Class members' claims have been tolled.

139. Alternatively, if the statute of limitations is not tolled, this Complaint alleges a continuing course of conduct (including conduct within the limitations period), and Plaintiff and the Class can recover damages they suffered during the limitations period.

XI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
For Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Violations of Section 1 of the Sherman Act (Against All Defendants)

140. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

141. The Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme designed to delay and block entry of AB-rated generic equivalents of Aggrenox. The intended and accomplished goal of the scheme was to use restrictive and exclusionary conduct to delay Barr and Teva's launch date for the first generic equivalent of Aggrenox. The Defendants injured Plaintiff and the Class through an agreement to exclude generic Aggrenox products from the market in exchange for substantial payments to Barr and Teva.

142. Had manufacturers of generic Aggrenox products entered the market and lawfully competed with Boehringer in a timely fashion, Plaintiff and the Class would have substituted lower-priced generic Aggrenox products for the higher-priced brand name Aggrenox for some or all of their purchases, and would have paid lower net prices on their remaining Aggrenox purchases.

143. The Defendants intended, and accomplished, a horizontal market allocation of the Aggrenox market, which is a per se violation of Section 1 of the Sherman Act. By their agreement, the Defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act. As a result of this unreasonable restraint on competition, Plaintiff and the Class paid artificially inflated prices for Aggrenox.

144. Plaintiff and the Class have suffered harm, and will continue to suffer harm in the future as a result of paying higher prices for Aggrenox than they would have absent Defendants' anticompetitive conduct and continuing anticompetitive agreement. Plaintiff and the Class also face a continuing threat of injury from the unlawful conduct alleged in this complaint.

145. Plaintiff and the Class have purchased substantial amounts of Aggrenox indirectly from Boehringer.

146. As a successor in interest to Barr, Teva is liable for all of Barr's anticompetitive conduct in connection with Aggrenox. And by joining an ongoing unlawful agreement to restrain trade, Teva is liable for all conduct that occurred prior to the date on which it joined the ongoing unlawful course of conduct. In addition, Teva is liable for its own unlawful conduct.

147. Plaintiff and the Class seek a declaratory judgment pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a) that the Defendants' conduct violates Section I of the Sherman Act.

148. Plaintiff and the Class also seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the Defendants' unlawful conduct, and other relief to ensure that similar anticompetitive conduct does not reoccur in the future.

SECOND CLAIM FOR RELIEF
For Violation of State Antitrust Laws
(Against All Defendants)

149. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

150. In 2008, Boehringer and Barr entered into the Exclusion Payment Agreement to suppress generic competition with Aggrenox. Teva joined and continued the unlawful agreement to suppress generic competition. The Exclusion Payment Agreement was and is a

contract, combination, and/or conspiracy that substantially, unreasonably, and unduly restrained trade in the relevant market, the purpose and effect of which was to:

a. Allocate all sales of Aggrenox in the United States to Boehringer until at least July 1, 2015;

b. Prevent each of the Defendants from selling a generic equivalent of Aggrenox in the United States until July 1, 2015;

c. Prevent Boehringer from competing against Barr/Teva with an authorized generic version of Aggrenox once Barr/Teva launches on July 1, 2015;

d. Fix the price that Plaintiff and the Class paid for Aggrenox; and

e. Fix the price that Plaintiff and the Class will pay for generic Aggrenox when it is launched on or after July 1, 2015.

151. The Exclusion Payment Agreement has harmed Plaintiff and the Class as set forth above.

152. The Exclusion Payment Agreement has covered a sufficiently substantial percentage of the relevant market to harm competition.

153. The Exclusion Payment Agreement is a horizontal market allocation and price-fixing agreement between actual and potential competitors and is illegal per se under state antitrust laws. Alternatively, Plaintiff alleges that the Exclusion Payment Agreement is an unreasonable restraint of trade, in violation of state antitrust laws.

154. There is and was no legitimate, non-pretextual, pro-competitive business justification for the Exclusion Payment Agreement that outweighs its harmful effect. Even if there were such a justification, the Exclusion Payment Agreement is and was broader than necessary to achieve any conceivable pro-competitive purpose.

155. The Defendants' conduct violated state antitrust laws:

a. Arizona Rev. Stat. §§ 44-1402, *et seq*., with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. Code §§ 16700, *et seq*., and Cal. Bus. Code §§ 17200, *et seq*., with respect to purchases in California by members of the Class.

c. D.C. Code Ann. §§ 28-4502, *et seq*., with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, et seq., with respect to purchases in Florida by members of the Class.

e. 740 III. Compo Stat. 10/3, *et seq*., with respect to purchases in Illinois by members of the Class.

f. Iowa Code § 553.2 *et seq*., with respect to purchases in Iowa by members of the Class.

g. Kan. Stat. Ann. §§ 50-WI, *et seq*., with respect to purchases in Kansas by members of the Class.

h. Mass. Gen. L. Ch. 93A, *et seq*., with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts End-Payors paying substantially higher prices for Aggrenox and its generic equivalents in actions and transactions occurring substantially within Massachusetts.

i. Me. Rev. Stat. Ann. 10, § 1101, *et seq*., with respect to purchases in Maine by members of the Class.

j. Mich. Comp. Laws Ann. §§ 445.772, *et seq*., with respect to purchases in Michigan by members of the Class.

k. Minn. Stat. §§ 325D.51, *et seq*., with respect to purchases in Minnesota by members of the Class.

l. Miss. Code Ann. §§ 75-21-3, *et seq*., with respect to purchases in Mississippi by members of the Class.

m. Neb. Code Ann. §§ 59-801, *et seq*., with respect to purchases in Nebraska by members of the Class.

n. Nev. Rev. Stat. Ann. § 598A.060, *et seq*., with respect to purchases in Nevada by members of the Class, in that thousands of sales of Aggrenox took place at Nevada pharmacies, purchased by Nevada end payors at supracompetitive prices caused by Defendants' conduct.

o. N.M. Stat. Ann. §§ 57-I-I, *et seq*., with respect to purchases in New Mexico by members of the Class.

p. New York General Business Law § 340, *et seq*., with respect to purchases in New York by members of the Class.

q. N.C. Gen. Stat. §§ 75-1, *et seq*., with respect to purchases in North Carolina by members of the Class.

r. N.D. Cent. Code § 51-08.1-02, *et seq*., with respect to purchases in North Dakota by members of the Class.

s. Or. Rev. Stat. §§ 646.705, *et seq*., with respect to purchases in Oregon by members of the Class.

t. 10 L.P.R.A. § 251, *et seq*., with respect to purchases in Puerto Rico by members of the Class.

u. R.I. Gen. Laws §§ 6-36-4 *et seq*., with respect to purchases in Rhode Island by members of the Class.

v. S.D. Codified Laws Ann. § 37-1-3.2, *et seq*., with respect to purchases in South Dakota by members of the Class.

w. Utah Code Ann. §§ 76-10-911, *et seq*., with respect to purchases in Utah by members of the Class.

x. Tenn. Code Ann. §§ 47-25-101, *et seq*., with respect to purchases in Tennessee by members of the Class, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Aggrenox and AB-rated generic equivalents at Tennessee pharmacies.

y. Vt. Stat. Ann. 9, § 2453, *et seq*., with respect to purchases in Vermont by members of the Class.

z. W.Va. Code §§ 47-18-3, *et seq*., with respect to purchases in West Virginia by members of the Class.

aa. Wis. Stat. § 133.03, *et seq*., with respect to purchases in Wisconsin by members of the Class, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for Aggrenox at Wisconsin pharmacies.

156. Plaintiff and the Class have been injured in their business or property by Defendants' antitrust violations. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

157. As a successor in interest to Barr, Teva is liable for all of Barr's anticompetitive conduct in connection with Aggrenox. And by joining an ongoing unlawful agreement to restrain trade, Teva is liable for all conduct that occurred prior to the date on which it joined the ongoing unlawful course of conduct. In addition, Teva is liable for its own unlawful conduct.

158. Plaintiff and Class members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of the Defendants' anticompetitive conduct.

159. Defendants are jointly and severally liable for all damages suffered by Plaintiff and the Class.

160. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the above-listed state antitrust laws.

THIRD CLAIM FOR RELIEF
For Unjust Enrichment
(Against All Defendants)

161. Plaintiff repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

162. Defendants have benefited from the overcharges on sales of Aggrenox made possible by the unlawful and inequitable acts alleged in this complaint.

163. Defendants' financial benefits are traceable to Plaintiff's and Class members' overpayments for Aggrenox.

164. Plaintiff and the Class have conferred an economic benefit upon the Defendants in the nature of profits resulting from unlawful overcharges, to the economic detriment of Plaintiff and the Class.

165. It would be futile for Plaintiff and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased

Aggrenox, as those intermediaries are not liable and would not compensate Plaintiff and the Class for Defendants' unlawful conduct.

166. The economic benefit Defendants derived from charging monopolistic and artificially inflated prices for Aggrenox is a direct and proximate result of Defendants' unlawful practices.

167. The financial benefits Defendants derived rightfully belong to Plaintiff and the Class, who paid anticompetitive prices that inured to Defendants' benefit.

168. It would be inequitable under unjust enrichment principles under the laws of each of the states in the United States and the District of Columbia and Puerto Rico for Defendants to retain any of the overcharges Plaintiff and Class members paid for Aggrenox that were derived from Defendants' unfair and unconscionable methods, acts, and trade practices.

169. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiff and the Class.

170. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiff and the Class.

171. A constructive trust should be imposed upon all unlawful or inequitable sums the Defendants received that are traceable to Plaintiff and the Class.

172. Plaintiff and the Class have no adequate remedy at law.

173. As a successor in interest to Barr, Teva is liable for all of Barr's anticompetitive conduct in connection with Aggrenox. And by joining an ongoing unlawful agreement to restrain trade, Teva is liable for all conduct that occurred prior to the date on which it joined the ongoing unlawful course of conduct. In addition, Teva is liable for its own unlawful conduct.

XII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, on its own behalf and on behalf of the proposed Class, demands a judgment that:

A. Determines that this case may be maintained as a class action pursuant to Federal Rule of Civil Procedure 23(a), (b)(2), and (b)(3), directs that reasonable notice of this case be given to class members under Rule 23(c)(2), and declares that Plaintiff is a proper representative of the Class;

B. Declares that Defendants' conduct violated Section 1 of the Sherman Act, the other statutes set forth above, and the common law of unjust enrichment;

C. Enjoins Defendants from continuing their illegal activities;

D. Enters joint and several judgments against Defendants and in favor of Plaintiff and the Class;

E. Grants Plaintiff and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy the Defendants' unjust enrichment;

F. Awards Plaintiff and the Class damages and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial, including interest;

G. Awards Plaintiff and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grants such further relief as the Court deems just.

XIII. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, demands a trial by jury on all issues so triable.

Dated: May 23, 2014

Respectfully submitted,

LOCKRIDGE GRINDAL NAUEN P.L.L.P.

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